In the United States Court of Federal Claims

No. 17-1158V
(Originally filed: November 6, 2023)
(Reissued: January 9, 2024)[1]

* *

NIKKO CERRONE,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

* *

OPINION

This is a case brought by Nikko Cerrone under the National Childhood Vaccine Injury Act seeking compensation for injuries he allegedly sustained as a result of receiving the human papillomavirus ("HPV"), influenza, and Hepatitis A ("Hep. A") vaccines on October 7, 2015. Mr. Cerrone filed a petition on August 28, 2017, alleging that the administration of at least one of these three vaccines caused the onset of his ulcerative colitis.

The matter is before the court on Petitioner's motion for review of the Chief Special Master's May 8, 2023 decision denying compensation. *Cerrone v. Sec'y of Health & Human Servs.*, No. 17-1158V, 2023 WL 3816718 (Fed. Cl. Spec. Mstr. June 1, 2023). The motion is fully briefed, and the oral argument is unnecessary. We deny the motion because the Chief Special Master applied the correct legal standards and did not abuse his discretion in concluding that Petitioner had not met his burden of proof.

BACKGROUND

[1] This opinion was originally issued under seal pursuant to Vaccine Rule 18(b). Because neither party notified the court of any necessary redactions, the full opinion is made public.

I. Factual History

The factual history of this claim is largely undisputed. A brief summary is necessary to understand the issues on review.[2] During a routine appointment with his primary care physician ("PCP") on October 7, 2015, Nikko Cerrone received three vaccines: one for HPV (under the "Gardasil" tradename), one for influenza (the "Flumist" formulation), and one for Hep. A. Petitioner was 16 years old and weighed 165.5 pounds at that time. There was no record made of any adverse reactions to the three vaccines during or immediately after this appointment.

None of Petitioner's medical records indicate any adverse vaccine reactions for the duration of 2015. Petitioner asserts, however, that he suffered three symptoms shortly after the immunizations. Pet's Aff.d (Oct. 12, 2017) (ECF No. 19- 1) ("Cerrone Aff. I"); Pet's Aff. (Mar. 20, 2018) (ECF No. 28) ("Cerrone Aff. II"). These symptoms include loss of stamina and lack of balance beginning in November 2015, Cerrone Aff. II at 2, and bloody stools starting in December 2015, *id.* at 1. As the Chief Special Master highlighted, however, at a February 10, 2016 appointment with his PCP for sore throat and congestion, Petitioner made no mention of these symptoms, and his physician recorded a normal abdominal examination. During this appointment Petitioner received a second dose of the Gardasil vaccine. There is no other contemporaneous evidence that Petitioner experienced any symptoms consistent with ulcerative colitis on or before February 10, 2016.

On February 13, 2016, Petitioner sought treatment in the emergency room of the Monroe Regional Hospital ("ER") for bloody stools. Mr. Cerrone complained at that time that he had been noticing bright red blood in his stool for roughly three weeks, with the problem increasing in severity over the days preceding his admission to the ER. After being diagnosed with hematochezia and then being discharged, Petitioner followed up with his PCP who referred him to a gastrointestinal specialist for evaluation.

A gastroenterologist performed a flexible sigmoidoscopy on Mr. Cerrone on March 14, 2016, finding ulcerations and inflammation in his colon. Petitioner's weight had dropped to 158 pounds by this point. After Petitioner followed up with his gastroenterologist ten days later, he was

[2] We provide here a summary of the Chief Special Master's extensive and thorough recitation of the facts of the case, which we adopt in full.

formally diagnosed with ulcerative colitis and irritable bowel disease ("IBD"). Mr. Cerrone was experiencing blood in his stool consistently at this point and was using suppositories in an effort to prevent such bleeding, to no avail.

Petitioner returned to the ER on May 19, 2016, for treatment of intestinal bleeding and abdominal pain, placing the start of symptoms (including diarrhea, constipation, abdominal pain, and hemorrhoids) at roughly five months earlier. He was prescribed more suppositories and fiber and was again discharged. He continued treatments to no avail. During a June 24, 2016 appointment with his PCP for an unrelated issue, Mr. Cerrone was administered a third dose of the Gardasil vaccine.

After continued unsuccessful treatment of his symptoms, Petitioner sought treatment at the Henry Ford IBD Center on October 3, 2016. During this visit, he told his physician that he had been experiencing bloody stools since December 2015. By this point he was moving his bowels 5 or 6 times per day, observing blood in his stool each time. He weighed 140 pounds, more than 25 pounds less than his recorded weight only one year earlier. Between October 2016 and early 2017, Petitioner continued various unsuccessful treatments. He was hospitalized multiple times during this period, including for surgery to remove a portion of his colon. He has since continued treatment under the guidance of multiple specialists and his PCP.

II. Procedural History

On August 28, 2017, Mr. Cerrone timely filed a petition for compensation, along with his medical records, under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to 300aa-34 ("Vaccine Act"). Petitioner alleged one of the three vaccines he was administered in October 2015 caused his ulcerative colitis.[3]

Respondent then filed a report recommending against compensation, arguing that Petitioner failed to satisfy the three prongs set out in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005), to establish causation. Respondent specifically asserted that Petitioner had not established a reputable medical theory or logical sequence of cause and effect

[3] Although petitioner argues on review that one of the three vaccines generally caused petitioner's ulcerative colitis, much of the discussion before the Chief Special Master centered on the Gardasil HPV vaccine.

connecting the Gardasil vaccine with his ulcerative colitis and that Petitioner had failed to establish an appropriate temporal association for a causal association between the administration of the Gardasil vaccine and the onset of his ulcerative colitis. The latter was true, Respondent argued, because the timing of the onset of Petitioner's ulcerative colitis symptoms was unclear from the evidence in the record—having occurred anywhere from 8 to 15 weeks after the vaccine was first administered.

On March 20, 2018, Petitioner provided a number of medical records and an affidavit detailing his symptoms along with a list of his high school activities. Petitioner also submitted expert reports from Dr. David Rosenstreich, M.D. and Dr. John Santoro, D.O. accompanied by supplemental medical literature in support of both reports. On January 14 and January 21, 2020, respectively, Respondent filed the responsive expert reports of Dr. Neil Romberg, M.D., and Dr. Chris Liacouras, M.D., also accompanied by medical literature.

The Chief Special Master held an entitlement hearing on May 24–25, 2022, at which he heard testimony from Drs. Rosenstreich, Liacouras, and Romberg. The Chief Special Master allowed for post-hearing briefing, after which he issued his decision denying compensation on May 8, 2023.

III. The Expert Opinions

After an extensive recitation of the factual and medical record background, the Chief Special Master's decision turned to a detailed analysis of the expert testimony. Petitioner's expert, Dr. Rosenstreich, an immunologist, provided two general theories of how Mr. Cerrone's vaccines could have caused his ulcerative colitis. First, Dr. Rosenstreich discussed molecular mimicry, a causal mechanism by which molecular similarities between different types of cells can cause the immune system to react similarly to both despite one being threatening (exogenous) and one being non-threatening (endogenous). Dr. Rosenstreich identified this as the most likely cause of Petitioner's gut inflammation. He hypothesized that certain proteins found in the Gardasil vaccine could have exhibited similarities to intestinal brush-border proteins, ultimately causing an abnormal immune reaction in the digestive system in which Mr. Cerrone's gut lining was attacked by his own immune system. He alternatively hypothesized that components of each of the three vaccines, such as alum adjuvant, could produce compounds in the body which would augment an abnormal immune response.

Dr. Rosenstreich also opined that the time frame of the onset of Petitioner's symptoms was consistent with a vaccine-caused illness. He testified that this was because of the general disease trajectory of ulcerative colitis. Inflammation would generally occur 30 days after the event originally causing the disease, at which point the body would reach peak antibody response. This response would cause large-scale cell death and regrowth in the gut, eventually creating holes in the gut when cells could not regrow to combat existing bacteria. This process would not cause visible bleeding for an additional 20 days. He placed the overall timeline of originating event to visible symptoms at roughly 80 days, which would align with Petitioner's stated onset of symptoms in late December 2015 after receiving his first Gardasil dose in October 2015.

Petitioner's other expert, Dr. Santoro did not testify at the hearing, and his contribution was largely duplicative of Dr. Rosenstreich's. He concurred with Dr. Rosenstreich's theory of molecular mimicry, and, in his report, stated that the vaccines likely caused Petitioner's ulcerative colitis because there was no other event that occurred near the onset of symptoms that could explain the disease. His most consequential contribution, as a gastrointestinal physician, was in concurring with Dr. Rosenstreich's assessment of the timeline and how it could be consistent with vaccine-cause illness. According to Dr. Santoro, because of the fluctuating nature of ulcerative colitis, there can be a significant time gap between first onset of symptoms and diagnosis, which could align with the trajectory of Mr. Cerrone's illness.

Respondent's experts disagreed with both the timing and causal analyses offered by Petitioner's experts. Dr. Liacouras testified primarily with respect to timing, asserting that the onset of Petitioner's symptoms was too temporally remote from the vaccine to suggest a causal connection. He noted that, although Petitioner later stated that he had first experienced bloody stools in December 2015, there was no documented evidence of such bleeding until late January 2016. Because Petitioner did not experience any immediate adverse response to any of his vaccine doses, and the documented onset of his ulcerative colitis symptoms was at least 14 weeks after the first administration of the vaccine, Dr. Liacouras found it unlikely that the vaccine caused Petitioner's ulcerative colitis.

Dr. Romberg's contribution focused almost entirely on discussing the mechanism of injury proposed by Petitioner's experts. Although he could not conclusively state that Gardasil-caused ulcerative colitis was impossible, he

assessed the chances in Petitioner's case to be near-zero. He dismissed Dr. Rosenstreich's theory regarding adjuvants, stating that adverse innate immune reactions to the substance would be evident within minutes of vaccination. Although Dr. Romberg admitted that molecular mimicry is a reputable scientific theory, he challenged the assertion that it could have been the vehicle for vaccine-caused ulcerative colitis. Dr. Romberg argued that Dr. Rosenstreich's theory failed to satisfy any part of a four-part framework used by many immunologists to assess whether molecular mimicry is the mechanism causing a given disease.[4]

IV. The Special Master's Decision

The Chief Special Master agreed with Respondent's experts and held that the Petitioner failed to meet his burden of proof under any of the three prongs of *Althen*: he did not demonstrate by a preponderance of the evidence "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a . . . proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278; *Cerrone*, 2023 WL 3816718, at *26. The Chief Special Master also specifically emphasized at the outset that Petitioner's burden of proof on the first prong entailed "establish[ing] that the vaccine(s) at issue more likely than not can cause the relevant disease." *Cerrone*, 2023 WL 3816718, at *26.

A. *Althen* Prong One

Regarding Dr. Rosenstreich's molecular mimicry theory, the Chief Special Master found that Petitioner had borrowed too much from studies implicating other vaccines and other autoimmune diseases. *Cerrone*, 2023 WL 3816718, at *27. Lacking was a connection to the injury suffered here. He emphasized that Dr. Rosenstreich, Petitioner's primary expert, did not

[4] The four parts, outlined in Dr. Romberg's report, were not included in the Chief Special Master's opinion. They are: (1) establishment of an epidemiological association between an infectious agent and the immune-mediated disease, (2) identification of T cells or antibodies directed against host target antigens in patients, (3) identification of microbial mimic of target antigen, and (4) reproduction of the disease in an animal model. C. Ang et al., *The Guillain-Barré Syndrome: A True Case of Molecular Mimicry*, 25 Trends Immunology 61, 62–64 (2004), filed as Ex. H (ECF No. 50-8).

specify which components of the vaccines would have mimicked the intestinal cells in Petitioner.[5] *Id.*

Petitioner's theory of an innate immune response to alum was likewise unpersuasive to the Chief Special Master. He found that there was little evidence that an alum adjuvant could cause Petitioner's illness and that any innate immune response to alum would likely be evident very soon after vaccination. *Id.* at *30. Lastly, the Chief Special Master weighed the credibility of the experts offered by Petitioner and Respondent. While he found that Dr. Rosenstreich was sufficiently credentialed to offer a good-faith opinion of how an immune response to a vaccine could cause a gastrointestinal illness, he was not able to buttress his arguments with clinical or research experience. *Id.* at *29.

Respondent's experts, on the other hand, relied on their firsthand research and clinical experience and to fair readings of the submitted literature to reject Dr. Rosenstreich's theories. *Id.* The Chief Special Master found the testimony of Drs. Liacouras and Romberg to be more objective and grounded in the facts of the case and the available literature, while Petitioner's experts were claim-oriented, in essence reasoning backwards from the injury to conclude a cause. *Id.* In the end, Petitioner had not established by preponderant proof that these vaccines could have caused his ulcerative colitis.

B. *Althen* Prong Two

Althen's second prong, under which petitioner must prove that the vaccine at issue did cause his illness, was likewise not met in the Chief Special Master's view. *See Althen*, 418 F.3d at 1278. Focusing on Petitioner's medical history, the Chief Special Master found little evidence of vaccine-caused illness. First, Petitioner's attending physicians never expressed any concern that vaccines were causing or worsening Petitioner's illness and even recommended further doses after the onset of ulcerative colitis. *Cerrone*, 2023 WL 3816718, at *29. Second, there was no evidence of an immediate inflammatory response to any doses of the vaccines. *Id.* at

[5] The Chief Special Master specifically dismissed the notion that he was holding petitioner to Dr. Romberg's stringent four-part test for proving the validity of a molecular mimicry theory, but he made explicit that he was taking into account Dr. Romberg's considerations in weighing the credibility of petitioner's evidence.

*29. Third, he found the evidence that subsequent doses of the vaccine had worsened Petitioner's ulcerative colitis lacking because Petitioner's symptoms worsened independently of (and often before) he received his second and third doses of the Gardasil vaccine. *Id.* at *30.

C. *Althen* Prong Three

The Chief Special Master concluded that Petitioner failed to establish a medically acceptable temporal association between vaccination and illness. *See Althen*, 418 F.3d at 1278. He found that there was insufficient evidence that onset of ulcerative colitis could occur as long as years after the initiating event. In addition, he also reasoned that Petitioner's theory of causal connection was inconsistent with Petitioner's earliest assertions of symptom onset. The Chief Special Master, relying on Dr. Romberg's testimony, noted that an innate immune response to the vaccines would be evident almost immediately after vaccination while Petitioner claimed that his first symptoms occurred roughly a month after vaccination. *Cerrone*, 2023 WL 3816718, at *30. The Chief Special Master also questioned Petitioner's claims regarding the onset of his ulcerative colitis symptoms. He found unconvincing the connection of Petitioner's earlier claimed fatigue and loss of stamina to his later diagnoses of ulcerative colitis, citing Dr. Liacouras' opinion that such symptoms would not occur because of ulcerative colitis until after a patient became anemic from rectal bleeding. *Id.* at *31.

In sum, the Chief Special Master found that Petitioner had failed to establish by a preponderance of the evidence all three *Althen* prongs. He was unconvinced by Petitioner's argument that the onset of illness at some point after vaccination is itself evidence of a connection between vaccine and illness. Because he found that Petitioner had failed to establish a medically sound theory of a biological mechanism of injury, that the medical record did not support Petitioner's theories in this case, and that the timeframe was quite attenuated, the Chief Special Master denied compensation. *Id.* at *32.

DISCUSSION

This court has jurisdiction to review a Special Master's decision pursuant to 42 U.S.C. § 300aa-12. Our review is deferential, only setting aside decisions when they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 300aa-12(e). Reversible error is "extremely difficult to demonstrate" when the Special Master has considered the relevant evidence and articulated a rational basis for the

decision. *Hines ex rel. Sevier v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). We may "not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." *Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011). On the other hand, we review a Special Master's legal determinations *de novo*. *See Munn v. Sec'y of the Dept. of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992)

Petitioners may seek compensation for "any illness, disability, injury, or condition" sustained or significantly aggravated by a vaccine. 42 U.S.C. §§ 300aa-11(c)(1) to 300aa-13(a)(1)(A). When a petitioner seeks compensation for an off-table injury (an injury other than those listed on the Vaccine Injury Table), petitioner must prove causation in fact. *Althen*, 418 F.3d at 1278 (citing 42 U.S.C. § 300aa-13(a)(1)(A)). A petitioner must demonstrate that the vaccination caused the injury by proving three elements by a preponderance of the evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.*

Different showings correspond to each of the elements, but the same evidence may be used to prove multiple elements. *Id*. First, a petitioner must provide a reputable medical theory that demonstrates a causal link between the vaccine at issue and the alleged injury. *Id.* A petitioner need not, however, satisfy this element with a specific type of evidence, propose a generally accepted theory, or demonstrate scientific certainty. *See Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378 (Fed. Cir. 2009). Yet a petitioner cannot prevail relying only on "a 'plausible' or 'possible' causal link between the vaccination and the injury; he must prove his case by a preponderance of the evidence." *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citing *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1332 (Fed. Cir. 2010)); *Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1360 (Fed. Cir. 2019). "[A] mere showing of a proximate temporal relationship between vaccination and injury" is likewise insufficient to prove actual causation. *Althen*, 418 F.3d at 1278.

Second, petitioner may use reputable medical or scientific evidence, including medical records, to demonstrate a logical sequence of cause and effect. *See Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006) (citations omitted). The treating physicians' opinions are also entitled to weight, particularly because they were formed contemporaneously with the onset of the illness at issue. *Id.* Third, petitioner must establish that there is a "medically-acceptable" period of time between the vaccination and alleged injury that is consistent with the causal theory linking the vaccine to the injury. *De Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

Petitioner here alleges that at least one of the vaccines administered to him in October 2015—the Gardasil HPV vaccine, Flumist flu vaccine, or the Hep. A vaccine—caused his ulcerative colitis. The Chief Special Master, however, concluded that Mr. Cerrone failed to satisfy any of the three *Althen* causation elements. Petitioner raises two issues on review. Although he frames both as legal challenges, one is a legal issue and the other is a challenge to the fact findings.

First, Petitioner asserts that the Chief Special Master erroneously interpreted and applied decisions such as *Althen* and *Andreu* by relying on *Boatmon* to reject plaintiff's argument with respect to the first *Althen* prong. Second, Petitioner argues that his evidence was only found to be insufficient because the Chief Special Master erroneously applied a heightened burden of proof to each element of Petitioner's claim. We evaluate legal issues *de novo* and factual determinations under an arbitrary and capricious standard.

I. The Chief Special Master Correctly Applied *Althen* and Its Progeny

Petitioner first argues that the Chief Special Master erred by relying on *Boatmon* to reject Petitioner's theory that medical plausibility could satisfy *Althen*'s first prong. This was error, Petitioner contends, because *Althen* and its progeny require nothing more than biological plausibility for a Petitioner to satisfy prong one. We disagree. *Althen* and its progeny have routinely rejected the contention that the first prong requires mere biological plausibility. It is clear from *Althen* that "the 'preponderance of the evidence' standard referred to in the Vaccine Act is one of proof by a simple preponderance, of 'more probable than not' causation," and that it applies to each of the three prongs. *Althen*, 418 F.3d at 1279 (citing *Hellebrand v. Sec'y of the Dept. of Health & Human Servs.*, 999 F.2d 1565, 1572–73 (Fed. Cir. 1993)); *Althen* 418 F.3d at 1276.

More recent Federal Circuit decisions regarding off-table injuries reaffirm that petitioners must prove *each* prong of the *Althen* analysis beyond mere plausibility. *See, e.g., Oliver v. Sec'y of Health & Human Servs.*, 900 F.3d 1357, 1361 (Fed. Cir. 2018); *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010); *LaLonde v. Sec'y of Health & Human Services*, 746 F.3d 1334 (Fed. Cir. 2014). Contrary to what Petitioner contends, *Boatmon* walks in lockstep with—and specifically references—this line of precedent by stating that the Federal Circuit has "reiterated that a 'plausible' or 'possible' causal theory does not satisfy the standard." *Boatmon v. Sec'y of Health & Human Services*, 941 F.3d 1351, 1360 (Fed. Cir. 2019).

Petitioner relies on *Andreu* and *Kottenstette* to counter this line of precedent, arguing that these decisions establish a standard of mere biological plausibility with respect to *Althen*'s first prong. Although *Andreu* does confusingly use the word "plausibility" to refer to petitioner's burden in that case, the decision elsewhere affirms that petitioner must prove her case by a preponderance of the evidence. *Andreu*, 569 F.3d at 1382. Likewise, *Kottenstette* merely found that a special master was correct in not requiring specific proof of a biological mechanism when the petitioner's causal theory satisfied "medical credibility." *Kottenstette ex rel C.K. v. Sec'y of Health & Human Servs.*, 861 F. App'x 433, 440 (Fed. Cir. 2021).

The Chief Special Master was therefore correct in concluding that mere biological plausibility falls below the required standard. *Cerrone*, 2023 WL 3816718, at *22, *26. He correctly stated the standard that Petitioner must meet: he must "*establish that the vaccine(s) at issue more likely than not can cause the relevant disease*." *Id.* at *26 (emphasis in original). The Chief Special Master specifically cited the relevant precedent on this issue, availing himself not only of *Boatmon* but also six other decisions from this court and the Federal Circuit standing for the same proposition.

We find that the Chief Special Master was correct in concluding that use of a "biological plausibility" standard on *Althen*'s first prong would *lower* the standard of proof below what is required by *Althen* and its progeny. The Chief Special Master did not err by relying on *Boatmon* and other similar cases to hold that petitioner must satisfy a more probable than not standard.

II. The Chief Special Master Did Not Abuse His Discretion in Finding Plaintiff's Evidence Deficient

We have established that the Chief Special Master did not err in applying a preponderance of the evidence standard to his *Althen* analysis. However, Petitioner also argues that the Chief Special Master applied an elevated standard of proof, and therefore abused his discretion by rejecting Petitioner's evidence. To prove this, Petitioner reargues the evidence he offered on each prong.

A. *Althen* Prong One

The lion's share of Petitioner's elevated standard of proof argument relates to prong one of the Chief Special Master's *Althen* analysis. First, Petitioner asserts that the Chief Special Master improperly rejected all of Petitioner's expert testimony out of hand. He supports this argument by quoting the Chief Special Master's assessment that Dr. Rosenstreich's testimony was more of a "claim-oriented desire to assist" than was the testimony of Respondent's experts. *Cerrone*, 2023 WL 3816718, at *29. This credibility assessment, Petitioner declares, is merely a disguise for the Chief Special Master's heightened evidentiary standard. Petitioner argues that this heightened evidentiary standard is reflected in the Chief Special Master's requiring reliable, independent medical evidence and testimony to preponderantly prove Petitioner's case.

We disagree. Far from an assessment of expert credibility being used to disguise this standard, the Chief Special Master makes clear that he found, after carefully and fairly juxtaposing each side's presentations, that Respondent offered the more reliable, independent evidence and testimony. His credibility determinations were a necessary part of that assessment. Contrary to Petitioner's assertion, the Chief Special Master did not dismiss Petitioner's experts out of hand but rather carefully considered their testimony in light of the contrary evidence. The assessment of an expert's credibility in deciding how much weight to afford their testimony is squarely within the discretion of a special master. *Moberly*, 592 F.3d at 1326; *Lampe v. Sec'y of Health & Human Services*, 219 F.3d 1357, 1362 (Fed. Cir. 2000).

We now turn to Petitioner's argument regarding the particulars of the evidence. Although Petitioner earlier insisted that the correct standard of proof was medical plausibility, he now argues that Mr. Cerrone proved that

the vaccines were the most likely cause of his illness by a preponderance of the evidence.

Petitioner notes that the experts agree that Mr. Cerrone likely suffers from ulcerative colitis and that ulcerative colitis is caused by a particular abnormal immune response. The experts also agree that vaccines may cause abnormal immune responses in some cases. It is after this that Petitioner's argument runs aground. He attempts to reframe Dr. Rosenstreich's testimony as a laser-focused, ironclad theory of how these three vaccines, when administered together, can cause ulcerative colitis. Respondent's experts, on the other hand, offered evidence from which the Chief Special Master concluded that Dr. Rosenstreich merely cobbled together unrelated evidence to speculate that molecular mimicry could be the vehicle for vaccines to cause ulcerative colitis. He found that Respondent's experts refuted the reliability of the evidence relied upon by Dr. Rosenstreich and therefore discredited the conclusions drawn by Petitioner.

Far from glazing over Petitioner's evidence, the Chief Special Master carefully examined each piece of evidence presented and explained why he evaluated it as he did. Regarding the literature, the Chief Special Master explained that much was related either to different vaccines than Mr. Cerrone received or to illnesses other than ulcerative colitis. Others, he found, relied on too small a sample size to be persuasive—citing Dr. Rosenstreich's own testimony that larger-scale studies are more reliable than those conducted on a small scale. *Cerrone*, 2023 WL 3816718, at *7. Contrary to Petitioner's assertion that such analysis of the evidence is the atomized approach of a "laboratorian," the Chief Special Master merely carefully examined the evidence in an attempt to assign the correct amount of weight to it in his analysis.

His assessment of the expert testimony likewise focused on reliability and credibility. Petitioner asserts that the experts merely disagreed on the relative weight of each piece of evidence, and that the Chief improperly substituted Respondent's expert opinions for Dr. Rosenstreich's. The Chief Special Master rather explained why he found Dr. Rosenstreich's testimony unpersuasive—particularly focusing on his lack of specific research experience on gastrointestinal disease and his theory's lack of reliable, independent scientific evidence. The Chief Special Master noted that Respondent's experts "were collectively more credentialed, better able to connect their testimony to their personal expertise, and proved significantly more persuasive . . . . based on their experiential understanding of the medical

scientific issues as well as fair readings of the filed literature." *Id.* at *29. He concluded that their testimony was more objectively related to the evidence provided, rather than Dr. Rosenstreich's "claim-oriented desire to assist" Petitioner's case, which resulted in his reasoning backwards to prove his causal theory. *Id.*

Our role in evaluating a special master's decision is not to quibble with the weight afforded certain pieces of evidence or substitute our determinations of credibility. Rather, we are empowered under the Vaccine Act only to act as a check on unreasonable decision-making. We find that the Chief Special Master here reasonably and appropriately weighed the evidence in rejecting Petitioner's claim.

B. *Althen* Prong Two

Regarding the second prong of causation, Petitioner essentially asserts that, because Mr. Cerrone's ulcerative colitis occurred at some point after he received the three vaccines at issue and Respondent provided no alternative causal factor, Petitioner's burden on *Althen*'s second prong is met. This misunderstands Petitioner's burden. Respondent is not required to prove some other causal factor in response to a petitioner's theory of causation. Rather, a petitioner must prove by a preponderance of the evidence not only that the vaccine *could have* caused petitioner's illness (under factor one) but also that it *did in fact* cause the illness in the case at hand. Respondent's experts focused on the weakness of Petitioner's evidence rather than proposing an alternative causal theory.

The Chief Special Master thoroughly explained this finding that the second prong of *Althen* was not satisfied. He discussed Mr. Cerrone's medical records, opining that they provided little evidence that Petitioner's ulcerative colitis occurred sooner than roughly four months after his initial vaccination. He noted that, even accepting Petitioner's assertions regarding onset of symptoms, the fatigue and instability he describes as occurring closer to vaccination are too nonspecific to warrant connection to his later ulcerative colitis. This finding was buttressed by the testimony of Drs. Liacouras and Romberg. *Id.* at *14, *21. He also observed that none of Petitioner's treating physicians thought the vaccines had caused or aggravated Petitioner's ulcerative colitis—as demonstrated by the fact that they recommended subsequent vaccine doses *after* the onset of his ulcerative colitis. *Id.* at *29.

The Chief Special Master explained clearly why the record did not support a logical sequence of cause and effect between Mr. Cerrone's vaccination and his illness. On review, Petitioner does not explain *why* this finding is erroneous, only insisting in a conclusory fashion that the Chief Special Master was illogical or unreasonable. We find that the Chief Special Master carefully weighed the evidence and clearly stated his reasoning.

C. *Althen* Prong Three

Petitioner is adamant that the Chief Special Master could not reasonably reject Petitioner's argument regarding prong three. But he merely reiterates Dr. Rosenstreich's testimony and asserts that it is more reliable than that of Respondent's experts. Again, it is not our role to question the weight afforded to different testimony or certain pieces of evidence by a special master. We are only to ensure that the Chief Special Master had a reasonable basis for his decision and adequately explained his reasoning.

The Chief Special Master clearly explained why he found that the temporal relationship between vaccination and illness was not medically acceptable. He reasoned that even Petitioner's earliest asserted symptom onset did not comport with his causal theory. Animal studies specific to ulcerative colitis and Respondent's expert testimony indicated that innate immune reactions to vaccines tend to occur almost immediately after vaccination, while Petitioner's symptoms did not begin until at least multiple weeks after vaccination. The Chief Special Master carefully evaluated the timing evidence presented by the parties in making his prong three determination. In doing so, he found that a period of 81 days between vaccination and illness was too attenuated to warrant compensation. We have no basis for overturning his decision.

CONCLUSION

The Vaccine Act requires only that we review a special master's opinion to ensure a reasonable basis for the decision and that the decision below was legally sound. Here, the Chief Special Master carefully considered all evidence presented by the parties and thoroughly explained his findings, including an account of the weight he afforded each piece of Petitioner's evidence. In the end, he found Respondent's experts to be better credentialed and their opinions to be more direct and well supported. In other words, he found that Petitioner had not met his burden of proof. This is just the sort of discretionary determination that is within a special master's

purview. We find no legal error in how the Chief Special Master applied Petitioner's burden of proof or in how he weighed the evidence.

Because the Chief Special Master committed no legal error and reasonably concluded that Petitioner fell short of his burden of proof, we affirm his decision. Accordingly, we deny Petitioner's motion for review. The clerk is directed to enter judgment accordingly.

s/Eric G. Bruggink
ERIC G. BRUGGINK
Senior Judge